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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/549,631

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Beate Schmidt

26964U

6178

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NATH & ASSOCIATES PLLC
112 South West Street
Alexandria, VA 22314

EXAMINER

BASQUILL, SEAN M

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

12/30/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/549,631	Applicant(s) SCHMIDT, BEATE	
	Examiner Sean Basquill	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17-27 is/are pending in the application.
- 4a) Of the above claim(s) 19-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 17 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>27 Aug 2009</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Previous Rejections

1. Applicants' arguments, filed ****, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of the Claims

2. Amendments to Claims 1, 10, 11, and 15 have been entered. Claim 16 has been canceled. Claims 19-27 remain withdrawn as directed to a nonelected invention.

Claims 1-15, 17 and 18 are presented for examination.

Claim Objections

3. Claim 10 stands objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Applicants arguments have been fully considered and are deemed unpersuasive. Claim 10 simply exchanges the chemical name for the chemical formula recited in Claim 1, thereby failing to introduce an additional limitation in a dependent claim. Applicants have clearly required an additional conformational limitation by requiring, in Claim 13, carbon 22 be in an R

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configuration, rather than S or an epimeric mixture of the two. Claim 10 imposes no such limitation. Indeed, in their response filed August 27th, applicants admit as such, indicating “the compound of Formula I is a compound with the chemical name 16,17-[(cyclohexylmethylene)bis(oxy)]-11-hydroxy-21-(2-methyl-1-oxopropoxy)pregna-1,4-diene-3,20-dione [11beta, 16alpha (R,S)],” which is the precise language presented in Claim 10. No further specification of chirality is included in this claim. Indeed, the specification indicates that either epimer, or any ratio of the combination of both epimers, falls within the meaning of “the compound of formula I.” As Claim ten merely substitutes the chemical name for the formula provided in Claim 1, no additional limitations on the scope of the invention claimed are presented, and Claim 10 fails to further limit the invention claimed.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-15, 17, and 18 stand rejected under 35 U.S.C. 103(a) as being unpatentable over International Patent Application WO98/09982 (hereinafter “Amschler”), in view of the Merck Index (1996).

As a threshold matter, the examiner has reviewed the Claim amendments presented by applicants in their submission filed 27 August 2009. The examiner notes that the additional phrase “a particle diameter for 50% of the total volume of all particles (X50) of less than or equal to 3um” represents the intended result of process steps positively recited, and as such is of no consequence in the construction of the claim for the purposes of examination. Nevertheless,

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assuming *arguendo* that the additional claim language does present an affirmative limitation, the examiner asserts that the particle size put forth in the instant claims would necessarily result from merely following the process steps as set forth.

Applicants arguments have been fully considered and are deemed unpersuasive. The examiner noted in the previous office action that while Amschler indeed disclosed the general conditions of the claims as put forth in the previous action, Applicants invention represented both a reshuffling of the order of the steps, as well as, in certain instances, a substitution of one solvent for another. However, as put forth in greater detail in the previous action, all process steps as claimed by applicants in the instant application were known to the skilled artisan prior to the filing of the instant application, and it is well known that the mere reshuffling of the order of process steps will not, without appropriate evidence of secondary indicia of nonobviousness, result in a patentable invention. *See In re Gibson*, 39 F.2d 975 (CCPA 1930) (indicating that in inventions describing a process, the selection of any order of mixing ingredients is *prima facie* obvious), *see also In re Mostovych*, 144 USPQ 38 (CCPA 1964) (indicating that in general, it is obvious to combine method of making steps which are individually known and complete in themselves, where the result is nothing more than the expected product). Indeed, the KSR decision cited by applicants in their response would seem to support the examiner's *prima facie* case, as they cautioned that "[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR v. Teleflex*, 82 USPQ2d 1385, 1395-96 (2007) (quoting *Sakraida v. A.G. Pro*, 425 U.S. 273, 282 (1976)). Indeed, the court warned of "the need for caution in granting a patent based on the combination of elements found in the

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prior art.” (*Id.* at 1395). Where, as here, applicants invention as claimed represents merely the rearrangement of known process steps and the substitution of one solvent well known for the purposes of recrystallizing organic chemical compounds, without appropriate secondary indicia of nonobviousness commensurate in scope with the invention as claimed, the claimed invention is obvious.

Conclusion

No Claims stand allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sean Basquill
Art Unit 1612

/JEFFREY S. LUNDGREN/
Primary Examiner, Art Unit 1639